REMARKS

In the Office Action dated April 21, 2009, claims 12-19, 21 and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Publication No. 2002/0179166 to Houston et al. (Houston) in view of U.S. Patent No. 5,709,713 to Evans et al. (Evans). Claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston in view of Evans and in further view of U.S. Patent No. 5,733,327 to Igaki et al. (Igaki). Claims 1, 3-6 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston in view of Evans and in further view of U.S. Patent No. 6,569,191 to Hogan (Hogan). Claims 9 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston in view of Evans and in further view of U.S. Patent No. 5,484,411 to Inderbitzen et al. (Inderbitzen). For the reasons outlined in detail below, it is respectfully submitted that the pending claims are in condition for allowance over the art of record.

Claims 12-19, 21 and 23

Claims 12-19, 21 and 23 were rejected as being unpatentable over Houston in view of Evans. With regard to independent claim 12, it was asserted that Houston discloses a conduit that may be a mesh stent 11 that appears to be expandable since it is disclosed as being collapsible. The stent is said to have an expanded configuration which is substantially free of ribs, and have a center line and helix angle of 8 degrees, that is within the claimed range of less than or equal to 65 degrees. It was admitted that Houston a) fails to disclose an amplitude having a value less than or equal to 0.7 of the internal diameter of the tubing, and b) to expressly disclose a stent that is expandable

from a collapsed configuration. However, it was asserted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing having a helical center line with a claimed value of an amplitude less than or equal to 0.7 of the internal diameter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

As to Evans, it was asserted to teach a mesh stent having a radially compressed and expanded configuration. It was then asserted that it would have been obvious to one having ordinary skill in the art at the time that the invention was made to have provided the mesh stent of Houston with an expansion and collapsing means as taught by Evans to release and remove the stent during and following the desired treatment. This rejection is respectfully traversed.

It is respectfully submitted that the Office Action misreads the embodiment of Figure 5 in Houston, as described in paragraph [0051]. First, it is only the Figure 5 embodiment of Houston that has a helical center line. As to Figure 5, paragraph [0051] describes an external device or structure which is used to impose a helical fluid path on a conduit which is disposed within the structure. More specifically, paragraph [0051] states:

> Thus a helical flow path can be induced within a conduit by means of the conformation imposed by a structure along its longitudinal axis . . . longitudinally coiled mesh structure 11 has a circular cross-section throughout is conformed to induce upon a conduit within it a helical flow pattern.

Thus, Houston discloses an external device which imposes a helical flow path on a conduit contained within the external device. In contrast, claim 12 recites an internal stent. Put another way, the mesh structure 11 in Houston is an external scaffold,

whereas the invention recited in claim 12 is directed towards a stent for insertion into a fluid conduit of a human or animal body, rather than an external scaffold placed around the fluid conduit.

Applicants respectfully submit that it would not have been obvious to a person of ordinary skill in the art to modify the stent of Figure 5 of Houston to be an internal stent, despite the mention of internal devices or structures in paragraph [0025] of Houston. There are a number of reasons for this.

First, there is a significant difference between the medical treatments for which external devices are employed, and those for which internal devices are used. Put another way, the uses external devices are put to are much different from the uses for internal stents. An external device requires open surgery on the patient so that a fluid conduit of a human or animal body is exposed and the external device can be placed around the fluid conduit. Thus, an external device would be used by a vascular surgeon. Second, structurally, such external devices, in order for them to be positioned around an intact vessel, would need to be longitudinally spread for deployment. If the device is to be positioned around a graft, then it could be threaded over an end of the graft before the graft is deployed. Third, in either case, an external device would require some means of attachment to the outside of the externally supported vessel. Such attachment means would make the external device unsuitable for use as an internal stent, as the attachment means would presumably block the vessel or fluid conduit. Thus, external devices are not designed to be provided in a collapsed condition for expansion to an expanded condition, as there is no reason for doing so.

On the other hand, an intravascular stent is installed in a relatively non-invasive

manner by an endovascular technique. The patient does not need to be opened up to allow access to the fluid conduit. The stent is provided in a collapsed condition so that it can be passed along a vessel to the site where treatment is required. At that location, the stent would then be expanded to its final use condition. Stents are used by different medical practitioners than external devices, namely, intervention cardiologists or intervention radiologists, as opposed to surgeons.

In view of the foregoing, external devices are considered by the art to be significantly different from internal stents. They are looked upon separately by not only medical specialists, but also by anyone skilled in the art. Therefore, a person skilled in the art would not ever consider modifying the external device of Figure 5 of Houston for use as an internal stent, as the structural modifications required would be quite major.

It is admitted that paragraph [0025] of Houston mentions that a structure could be placed inside or outside a blood vessel. However, the mention of inside structures in Houston does not apply to the embodiment of Figure 5, which is quite clearly described as an external device.

Furthermore, paragraph [0025] of Houston states in pertinent part that:

> A structure according to the present invention could be placed inside or outside the blood vessel to impose, maintain and/or reinforce a flow guiding formation through the blood vessel.

Thus, in order for the structure according to Houston to be placed inside the blood vessel, that structure would comprise a flow guiding formation, much less disclose one. This is an essential feature of paragraph [0025] of Houston and is a fourth significant difference. In contrast, the embodiment of Figure 5 and paragraph [0051]

does not even mention such a flow guiding formation much less disclose one. Therefore, a person skilled in the art would understand that the teaching of paragraph [0025] of Houston is not relevant to Figure 5 of Houston, as Figure 5 excludes the essential feature of a flow guiding formation. Rather, such a person would understand that the teachings of paragraph [0025] of Houston are relevant only to those structures that have a flow guiding formation comprising ridges and grooves, such as are described in paragraph [0014] of Houston. For this reason as well, a person of ordinary skill in the art would not have found it obvious to modify the embodiment of Figure 5 of Houston, according to paragraph [0025] of Houston. Instead, these two disclosures of Houston are significantly different and relate to structurally incompatible embodiments of a flow means.

Put another way, where Houston teaches the person of ordinary skill in the art about internal stents, that teaching is to a stent which has a flow guiding formation provided by ridges or grooves, such as ridges 4a, 4b and 4c in Figure 2. On the other hand, where Houston teaches a coiled longitudinal device without ridges and grooves, such as in Figure 5, the teaching is to an external device only. Tellingly, there is no teaching in Houston of a collapsible internal stent with a helical center line and no ribs. Therefore, even if a person of ordinary skill in the art wished to modify the Houston apparatus to be of a collapsible and internal type, he would retain the flow guiding formation comprising ridges or grooves. But, such a modified stent would fall outside the scope of claim 12, as claim 12 recites a stent which in the expanded condition is substantially free of ribs which would project into the flow lumen of the conduit.

The teachings which are clearly absent from Houston are not provided by the

secondary reference to Evans. Evans discloses a tubular prosthesis which is implanted at a target location within a body lumen. But, as noted, if a person of ordinary skill in the art wished to combine the teachings of Houston with Evans, the resultant device would be of a collapsible and internal type as disclosed by Evans, but retaining the flow guiding formation comprising ridges and grooves as is taught by Houston. Those ridges and grooves are located on the internal periphery of the stent. This is in contrast with the claimed invention which, as mentioned, recites a stent that in the expanded condition is substantially free of ribs which would project into the flow lumen of the conduit.

It was also stated in the Office Action that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of Houston with the expansion and collapsing means taught by Evans to release and remove the stent during and following desired treatment. In this connection, Applicants note that once the collapsed stents are expanded, they are not collapsed again for release and removal. Rather, the stents are permanently placed in a fluid vessel of the patient. As noted in the instant specification, stents are generally manufactured in the collapsed condition, ready for delivery into a fluid conduit of the patient, and then are expanded into the expanded condition when inside the fluid vessel or other fluid conduit of the patient (see page 1, lines 11-19). Once the outer wall of the stent engages the inner wall of the fluid conduit, the stent stays in place. It has to because any movement of the stent would be harmful or dangerous to the patient. At any rate, even the combination of Houston and Evans neither teaches nor discloses the subject matter which is recited in pending independent claim 12. Therefore, it is

respectfully submitted that independent claim 12 patentably defines over even the combination of Houston and Evans, as well as the remainder of the cited art.

Dependent claims 13 and 15-19, 21 and 23 merely further patentably define the detailed subject matter of their parent claim. Therefore, these claims are also believed to be in condition for allowance over the art of record. It is noted that claim 14 has been canceled without prejudice.

Claim 20

Claim 20 was rejected over Houston in view of Evans and in further view of Igaki. In this connection it was asserted that Igaki teaches a coating for a stent to provide locally limited and long-term dosage of drugs. However, even the asserted three-way combination neither teaches nor discloses the subject matter recited in claim 20. Particularly, even the asserted three-way combination neither teaches nor discloses a stent for insertion into a fluid conduit wherein the stent in the expanded condition is substantially free of ribs which would project into the flow lumen of the conduit. There is no teaching or disclosure in Igaki which would alter the structure taught in Houston concerning internally extending ribs which project into the flow lumen of the conduit. Therefore, claim 20 is also believed to be in condition for allowance over the asserted combination of references, or the remainder of the cited art.

Claims 1, 3-6 and 22

These claims were rejected over the combination of Houston and Evans in further view of Hogan. It was stated that Hogan teaches an expandable stent where rigid longitudinal strips 40 are attached to the helically wound threads that form the wall

of the stent and exert an increased longitudinally constricting force. However, even the asserted three-way combination neither teaches nor discloses the subject matter which is recited in claims 1, 3-6 and 22. More specifically, even the applied three-way combination fails to show a stent for insertion in a fluid conduit of a human or animal body, wherein the stent in the expanded condition is substantially free of ribs which would project into the flow lumen of the conduit. There is no teaching or disclosure in Hogan which would change the description of Houston of internally extending ribs of a stent which project into the flow lumen of the conduit. Therefore, these claims are also patentable over the applied three-way combination of references.

Claims 9 and 10

These claims were rejected as being unpatentable over Houston in view of Evans and in further view of Inderbitzen. Inderbitzen was employed for its teaching of an expandable balloon used in angioplasty procedures, including a longitudinally extending spiral wall 38 extending from the distal to the proximal end of the balloon. The spiral wall is said to be formed integrally with the exterior surface of the balloon and radially restricts the expansion of the balloon along the longitudinally extending spiral path.

However, even this applied three-way combination fails to teach or disclose the claimed subject matter of claims 9 and 10, namely, a stent for insertion in a fluid conduit, wherein the stent in its expanded condition is substantially free of ribs which would project into the flow lumen of the conduit. The Inderbitzen reference does not supply those teachings which are clearly absent from the combination of Houston and Evans, as discussed above. Therefore, dependent claims 9 and 10 are also believed to

be in condition for allowance over the applied three-way combination, as well as the remainder of the cited art.

New Claims

Applicants present herewith new independent claim 24 and dependent claims 25-28.

Claim 24 recites a stent for insertion in a fluid conduit of a human or animal body when the stent is in a collapsed condition and for expansion to an expanded condition. In the expanded condition, the stent has a center line which follows a substantially helical path so as to promote swirl flow within the fluid conduit supported by the stent. The stent when expanded *ex vivo* has a helix angle less than or equal to 65 degrees, and a helical center line having an amplitude less than or equal to 0.7 of the internal diameter of the stent. In the expanded condition, the stent is substantially free of ribs which would project into the flow lumen of the conduit. The helical center line of the stent varies to introduce a gentle swirl at an upstream end of the stent and to increase the swirl effect in a downstream direction.

Claim 24 recites a feature that is not present in independent claim 12, namely, that the helical center line varies to introduce a gentle swirl at an upstream end of the stent and to increase the swirl effect in a downstream direction. This subject matter is not new, as it was present in the application as filed. More particularly, it is stated in the specification that the amplitude and pitch of the helical center line can be chosen to vary along the length of the stent if desired. Variation of the amplitude can be achieved by increasing or decreasing the resistance to extension provided by the helical portion,

while variation in pitch may be achieved by varying the pitch of the helical portion itself. Such variations may be desired if it is wished to introduce a gentle swirl at the upstream end of the stent and to increase the swirl effect in the downstream direction (see the instant specification, page 6, lines 28-37). Therefore, no new subject matter is being disclosed.

As to independent claim 24, there is no disclosure or suggestion of such a varying helical center line either in the applied primary reference to Houston or in any of the secondary references to Evans, Igaki, Hogan or Inderbitzen. Not only is claim 24 patentable because of its recitation of a) a stent for insertion in a fluid conduit wherein the stent, in the expanded condition, is substantially free of ribs which would project into the flow lumen of the conduit, but it is also in patentable condition over the applied art because of its recitation b) that the helical center line varies to introduce a gentle swirl and to increase the swirl effect in a downstream direction.

Dependent claim 25 recites that the angle of the helical center line varies along the length of the stent. No teaching or disclosure of such a stent is present in any of the applied references. Therefore, claim 25 is also in condition for allowance over the applied art, or any of the remainder of the cited art.

Dependent claim 26 recites that the amplitude of the helical center line varies along the length of the stent. Claim 27 recites that the pitch of the helical center line varies along the length of the stent. Finally, claim 28 recites that both the amplitude and the pitch of the helical center line vary along the length of the stent. This subject matter is amply disclosed in the patent application as filed on page 6, lines 28-37. However, none of the subject matter recited in these claims is taught or disclosed in any of the

applied references, or the remainder of the cited art. Therefore, these claims are also patentable over the applied references, in any combination.

SUMMARY

In view of the foregoing arguments, it is respectfully submitted that the pending claims are in condition for allowance over the all of the applied references, as well as the remainder of the cited art. Allowance of the pending claims is therefore earnestly solicited.

Respectfully submitted,

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